

Applicant : Wei-Yu Lo et al.  
Serial No. : 09/778,516  
Filed : February 7, 2001  
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Attorney's Docket No.: 12875-002001 / 0643-5299US

### REMARKS

This document is filed in reply to the final Office Action dated December 15, 2004 ("Office Action"). Applicants have cancelled claims 15 and 16, and deleted "SEQ ID NO:7" and "SEQ ID NO: 8" from the Specification in view of the cancellation. No new matter has been introduced.

Claims 1-14 are pending and under examination. Reconsideration of this application is requested in view of the following remarks:

#### Objection to the Specification

The Examiner objected to the Specification on two grounds. Applicants traverse each ground below.

First, it is the Examiner's position that "[t]he specification contains sequence disclosures that are not identified by SEQ ID NO[s] (e.g., page 14, lines 24-25 and page 15, lines 16-17)." See the Office Action, page 2, second paragraph.

Applicants respectfully traverse. The two passages of the Specification at issue disclose four PCR primers. Applicants would like to point out that these primers, as well as other sequences disclosed in the Specification, are identified by SEQ ID NOs. See the amendments to the Specification submitted with Applicants' Response To Notice To Comply With Requirements For Patent Applications Containing Nucleotide And/Or Amino Acid Sequences mailed July 10, 2001 (copy attached hereto as "Exhibit A").

Second, the Examiner objected to Applicants' previous amendment to the Specification at page 7, lines 21-28 for introducing new matter. See the Office Action, page 6, lines 1-15. In the sole interest of moving this case toward allowance, Applicants have deleted the alleged new matter, thereby rendering this objection moot.

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Rejection under 35 U.S.C. § 112, first paragraph

The Examiner maintained the rejections of claims 13, 15, and 16 on two grounds. Applicants have cancelled claims 15 and 16, and will only address the rejection of claim 13 below:

Claim 13, drawn to a DNA immunogenic composition, is rejected for lack of enablement. See the Office Action, page 3, lines 1-3. According to the Examiner, "there is no asserted utility other than vaccination, which is not enabled by the disclosure." See the Office Action, page 4, lines 3 and 4. Applicants submit that (1) there is asserted utility other than vaccination; and (2) the asserted utilities are enabled.

First, the Specification clearly teaches a number of non-vaccination utilities of the claimed composition. For example, the composition can contain a recombinant expression Lac shuttle vector encoding a heterologous protein,<sup>1</sup> and "[t]he heterologous protein of interest thus can be *in vivo* or *in vitro* overexpressed in a suitable eukaryotic cell ... [or] an appreciate prokaryotic cell (emphasis added)." See page 11, lines 7-23. Since the claimed composition has *in vitro* utilities and vaccination is an *in vivo* utility, it follows that "there is [an] asserted utility other than vaccination" in the Specification.

Second, the Specification provides sufficient teachings as to how to use the composition of claim 13. For example, it teaches that *in vitro* expression of a heterologous protein "can be achieved via various mechanisms known to those skilled in the art[, e.g.], transformation, (including treatment with divalent cation, DMSO, reducing reagent, hexamminecobalt chloride and so on), electroporation or particle bombardment." See page 3, lines 17-23. As all of these techniques are routine, claim 13 meets the enablement requirement.

<sup>1</sup> This passage teaches compositions containing the recombinant expression Lac shuttle vector. More specifically, it states that the vector can be used "with divalent cation, DMSO, reducing reagent, hexamminecobalt chloride and so on." See lines 21 and 22.

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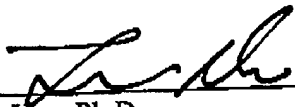
### CONCLUSION

Applicants submit that the rejections asserted by the Examiner have been overcome, and that the claims define subject matter that is enabled and free of new matter. Allowance of this application is therefore proper, and early favorable action is solicited.

Please apply any other charges or credits to deposit account 06-1050, referencing attorney docket 12874-002001.

Respectfully submitted,

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